Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

1. (Currently amended) A method of preparing a lyophilized composition comprising:

   (a) mixing

      (i) polyoxyethylene (POE) and polyoxypropylene (POP) blockcopolymer;

      (ii) a polynucleotide;

      (iii) a cationic surfactant; and

      (iv) ~~an amorphous cryoprotectant~~ a compound selected from the group consisting of monosaccharides, disaccharides, oligosaccharides, sorbitol, hydrophilic polymers, proteins and mixtures thereof ~~or a crystalline bulking agent~~;

   at a temperature below the cloud point of said block copolymer to form a mixture; and

   (b) lyophilizing the mixture.

2. (Original) The method of claim 1, wherein said block copolymer is of the general formula: $HO(C_2H_4O)_x(C_3H_6O)_y(C_2H_4O)_xH$; wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C_3H_6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of the hydrophilic POE portion (C_2H_4O) is between approximately 1% and 50% by weight.

3. (Original) The method of claim 1, wherein said block copolymer is of the general formula: HO $(C_3H_6O)_y(C_2H_4O)_x(C_3H_6O)_yH$; wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C_3H_6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of the hydrophilic POE portion (C_2H_4O) is between approximately 1% and 50% by weight.

4. (Original) The method of claim 1, further comprising a cold filtration step.

5. (Original) The method of claim 1, wherein said mixing step (a) is performed at a temperature of about -2°C to about 8°C.

6. (Original) The method of claim 4, wherein said cold filtration step is performed at a temperature of about -2°C to about 8°C.

7. (Original) The method of claim 4, wherein said cold filtration step is performed using a filter with a pore size of about 0.01 microns to about 2 microns.

8. (Original) The method of claim 2, wherein said block copolymer is CRL-1005.

9. (Original) The method of claim 1, wherein the cationic surfactant is selected from the group consisting of benzalkonium chloride (BAK), benethonium chloride, cetrimide, cetylpyridinium chloride, acetyl triethylammonium chloride, (±)-N-(Benzyl)-N,N dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (Bn-DHxRIE), (±)-N-(2 Acetoxyethyl)-N,N-dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (DHxRIE-OAc), (±)-N-(2-Benzoyloxyethyl)-N,N-dimethyl-2,3-bis(hexyloxy)-1 propanaminium bromide (DHxRIE-OBz) and (±)-N-(3-Acetoxypropyl)-N,N dimethyl-2,3-bis(octyloxy)-1- propanaminium bromide (Pr-DOctRIE-OAc).

10. (Original) The method of claim 1, wherein said mixture comprises at least one amorphous cryoprotectant.

11. (Original) The method of claim 10, wherein said amorphous cryoprotectant is sucrose.

12. (Original) The method of claim 1, wherein said mixture comprises at least one crystalline bulking agent.

13. (Original) The method of claim 1, wherein said mixture comprises about 1% to about 20% (w/v) of said amorphous cryoprotectant or crystalline bulking agent.

14. (Original) The method of claim 11, wherein the final concentration of sucrose is about 10% (w/v).

15. (Original) The method of claim 1, wherein said mixture additionally comprises a pH stabilizing physiologic buffer.

16. (Original) The method of claim 15, wherein said physiologic buffer is selected from the group consisting of: saline, PBS, HEPES, MOPS, BIS-TRIS, sodium phosphate, potassium phosphate, dibasic sodium phosphate (Na_2HPO_4), monobasic sodium phosphate (NaH_2PO_4), monobasic sodium potassium phosphate ($NaKHPO_4$), magnesium phosphate ($Mg_3(PO_4)_2 \cdot 4H_2O$), or D(+)-α-sodium glycerophosphate ($HOCH_2CH(OH)CH_2OPO_3Na_2$).

17. (Original) The method of claim 16, wherein said physiologic buffer is sodium phosphate.

18. (Original) The method of claim 15, wherein the concentration of said physiologic buffer in the mixture is from about 5 mM to about 25 mM.

19. (Original) The method of claim 17, wherein said sodium phosphate is at a concentration of about 5 mM to about 25 mM.

20. (Original) The method of claim 1, wherein the final concentration of said cationic surfactant present in said mixture is from about 0.01 mM to about 5 mM.

21. (Original) The method of claim 1, wherein the final concentration of said block copolymer present in said mixture is from about 1mg/mL to about 50mg/mL.

22. (Original) The method of claim 1, wherein the final concentration of said polynucleotide molecules present in said mixture is from about 1ng/mL to about 10mg/mL.

23. (Original) A product produced by the process of claim 1.

24. (Original) A stable, mono-dispersed product produced by reconstituting the product of claim 23 with an aqueous solution.

25. (Original) A product produced by the process of claim 4.

26. (Original) A stable, mono-dispersed product produced by reconstituting the product of claim 25 with an aqueous solution.

27. (Original) A product produced by the process of claim 15.

28. (Original) A stable, mono-dispersed product produced by reconstituting the product of claim 27 with an aqueous solution.

29. (New) The method of claim 9, wherein said cationic surfactant is benethonium chloride.

30. (New) The method of claim 9, wherein said cationic surfactant is cetrimide.

31. (New) The method of claim 9, wherein said cationic surfactant is cetylpyridinium chloride.

32. (New) The method of claim 9, wherein the cationic surfactant is acetyl triethylammonium chloride.

33. (New) The method of claim 9, wherein said cationic surfactant is (±)-N-(Benzyl)-N,N dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (Bn-DHxRIE).

34. (New) The method of claim 9, wherein said cationic surfactant is (±)-N-(2 Acetoxyethyl)-N,N-dimethyl-2,3-bis(hexyloxy)-1-propanaminium bromide (DHxRIE-OAc).

35. (New) The method of claim 9, wherein said cationic surfactant is (±)-N-(2-Benzoyloxyethyl)-N,N- dimethyl-2,3-bis(hexyloxy)-1 propanaminium bromide (DHxRIE-OBz).

36. (New) The method of claim 9, wherein said cationic surfactant is (±)-N-(3-Acetoxypropyl)-N,N dimethyl-2,3-bis(octyloxy)-1- propanaminium bromide (Pr-DOctRIE-OAc).

37. (New) The method of claim 1, wherein said compound is one or more monosaccharides.

38. (New) A product produced by the process of claim 37.

39. (New) A stable, mono-dispersed product produced by reconstituting the product of claim 38 with an aqueous solution.

40. (New) The method of claim 1, wherein said compound is one or more disaccharides.

41. (New) A product produced by the process of claim 40.

42. (New) A stable, mono-dispersed product produced by reconstituting the product of claim 41 with an aqueous solution.

43. (New) The method of claim 1, wherein said compound is one or more oligosaccharides.

44. (New) A product produced by the process of claim 43.

45. (New) A stable, mono-dispersed product produced by reconstituting the product of claim 44 with an aqueous solution.